Title: PROTECTIVE GARMENT WITH A HAND SHIELD SUITABLE FOR ITS UNASSISTED DONNING

Abstract: A protective garment (24) having a sleeve (22) that possesses an interior region and a peripheral surface (34) attached to a hand shield (10). The hand shield (10) also has an interior region and a peripheral opening (32). The peripheral opening (32) of the hand shield (10) is attached to and shares a common border with the peripheral surface (34) of the sleeve (22) thereby enabling direct access between the interior regions of the sleeve (22) and the hand shield (10). The hand shield (10) is designed to be detached from the sleeve (22) at a zone of separation 30 without damaging the sleeve (22). Use of this protective garment (24) is conducive to methods for the unassisted donning of sterile gloves.
PROTECTIVE GARMENT WITH A HAND SHIELD SUITABLE FOR ITS UNASSISTED DONNING

BACKGROUND OF THE INVENTION

The present invention relates generally to the sterile donning of gloves, more specifically, to the unassisted sterile donning of gloves that may be designed to be used in conjunction with protective garments.

Gloves, including surgical gloves, are worn in a variety of environments that demand sterility, for example, the medical, food-preparation and manufacturing "clean room" environments. In the medical environment, gloves are worn to prevent the hands of medical professionals from contacting a patient's body during a physical examination or a surgical operation. They are universally recognized as a major safeguard against the risk of inadvertent or accidental infection of the patient in the administration of medical and dental treatment. Wearing nonsterile gloves in such an environment may lead to infection of the patient. In the "clean room" environment, gloves are worn to prevent the hands of a technician from directly contacting items, such as wafers and other devices supporting highly sensitive electronic circuits. Wearing nonsterile gloves in such an environment may lead to contamination of such items, making them unsuitable for use.

As such, these gloves are manufactured to be sterile. Sterility of the glove can be adversely affected during the process in which the wearer puts on or dons the glove. During this process, the hands can contact and contaminate the gloves by the inadvertent transfer of microbes found on the wearer's hands to the sterile glove surfaces. Ordinarily, at least in the case of the medical profession, the risk of undesirable contamination in this process is reduced by putting the glove on by using one of two generally accepted fashions or techniques for unassisted donning; that is, open glove donning or closed glove donning.

The open glove donning technique now used for donning gloves, for example surgical gloves, requires that the sealed package containing the sterile gloves be carefully opened so that the inner surfaces of the package, and more particularly, the outside surfaces of the gloves contained therein, do not come in contact with any nonsterile surface. As such, the gloves are usually packaged with their cuffs everted; that is, turned inside out and folded downwardly. To don the right glove, one grasps the right glove on the fold of the everted cuff with the left hand and the right hand is inserted into the glove opening. Next,
the left glove is picked up and held with the right hand by slipping the gloved fingers of that hand underneath the everted cuff while the left hand is inserted into the glove opening. To complete glove donning the everted cuffs are carefully pulled over the distal ends of the garment's sleeves so that the entirety of the previously exposed surfaces of the everted cuffs are on the insides of the gloves and the outsides remain untouched by ungloved hands.

In the closed glove donning technique, the gloves are handled through the fabric of the sleeve itself, for example a surgical gown sleeve. As such, the wearer's hand does not extend outside from the sleeve until the open end of the glove is actually pulled over the sleeve. The closed glove donning technique may best be conveyed by describing its current use in a surgical arena. This method assumes that the wearer is already wearing a sterile surgical gown. Accordingly, the wearer uses the left hand while keeping it within the sleeve of the gown to pick up the right glove by its everted cuff. In this manner, the glove itself is not directly touched since the left hand is shielded by the sleeve. With the right hand extended palm upward but retained occluded within the sleeve, the left hand places the palm of the glove with fingers pointing towards the wearer against the occluded palm of the right hand. The closest edge of the everted cuff is grasped by the right hand through the sleeve fabric. Next, the left hand pulls the ungrasped everted cuff edge over the right sleeve and hand. The left hand is gloved in the same manner using the gloved right hand to appropriately place the left glove and pull it over the left sleeve and hand.

Both glove donning methods entail difficulties: open glove donning requires a high level of finger and hand dexterity; closed glove donning suffers from finger and hand dexterity being hampered while one's fingers remain shielded by the sleeve. As would be expected by such complex procedures, they are susceptible to numerous accidental contamination possibilities, especially during times of distress and urgency. Thus, a need exists that would enable a wearer to don an unattached glove effectively and in an aseptic manner. Such a method would have an added advantage if it could be performed without necessitating the help of an assistant, more so if it were also economically cost effective to implement and practice.
SUMMARY OF THE INVENTION

Objects and advantages of the invention will be set forth in part in the following description, or may be obvious from the description, or may be learned through practice of the invention.

The present invention provides a protective garment. The garment itself includes a garment body having sleeves, each sleeve terminating in an open end, and a hand shield attached to at least one of the sleeves. The hand shield is essentially a pouch-like compartment which has a peripheral opening aligned with and having a common border with a peripheral surface of the sleeve. This structure is adapted to receive a portion of a wearer's hand therethrough and contain it within the compartment. At least a portion of the hand shield is detachable from the sleeve at a zone of separation and may be so detached without damaging the sleeve. The invention may be especially well suited to surgical gowns, clean room garments, and work wear. The hand shield may be made of a film, may be made of the same material as the sleeve material, or may be made of various other polymers and/or plastisols. The physical configuration of the hand shield may take the form of a glove, a mitt, and/or a pouch.

In another embodiment, the invention provides a sleeve that may be used alone or in conjunction with a protective garment. In this embodiment, the sleeve may have an interior region, an opening, and a peripheral surface. A hand shield having an interior region and a peripheral opening is attached to and shares a common border with the peripheral surface of the sleeve enabling direct access between the interior regions of the sleeve and the hand shield. At least a portion of the hand shield is detachable from the sleeve at a zone of separation without damaging the sleeve.

The invention provides an advantage enabling the wearer to gain additional dexterity while donning a sterile glove in an aseptic manner. In this way, the invention addresses at least certain of the disadvantages of conventional glove donning solutions currently available in the market and discussed above. It should be appreciated that, although the present invention has particular usefulness in the surgical arena, particularly in its use with a surgical gown, the invention is not limited in scope to surgical gowns or the medical industry. The hand shield used with or without a protective garment according to the present invention has wide application and can be used in any instance where a protective coverall, gown, robe, etc., is used with gloves. All such uses and garments are
contemplated within the scope of the invention. These and other objects are achieved by the process disclosed and claimed herein.

**BRIEF DESCRIPTION OF THE FIGURES**

FIGs. 1A-1C are perspective views of embodiments of a protective garment containing three different hand shield configurations according to the present invention;

FIG. 2 is a partial perspective view of a garment sleeve according to an embodiment of the present invention;

FIG. 3 is a partial perspective view of an alternative garment sleeve according to an embodiment of the invention; and

FIG. 4 is a partial perspective view of another garment sleeve according to an embodiment of the present invention; and

FIG 5 is a partial perspective view of still another garment sleeve according to an embodiment of the present invention.

**DETAILED DESCRIPTION OF THE INVENTION**

Reference will now be made in detail to one or more examples of the invention depicted in the FIGs. Each example is provided by way of explanation of the invention, and not meant as a limitation of the invention. For example, features illustrated or described as part of one embodiment may be used with another embodiment to yield still a different embodiment. Other modifications and variations to the described embodiments are also contemplated within the scope and spirit of the invention.

FIGs. 1A, 1B, and 1C illustrate various embodiments of a disposable hand covering or hand shield 10 according to the invention. Numerous configurations of the hand shield 10 are possible including that shown in FIG. 1A wherein the hand shield 10 is configured as a pouch-like compartment or receptacle capable of receiving at least a portion of a wearer's hand therein. In another embodiment, the hand shield 10 may be configured as a mitten or mitt 12 having a finger compartment 14 separate from a thumb compartment 16 as depicted in FIG. 1B. In another embodiment, depicted in FIG. 1C, the hand shield 10 may be configured as a glove 18, that is, it may have a separate cot 20 for each finger, including the thumb. In any of the embodiments, the hand shield may be designed to be one-size-fits-all without negatively impacting its function or design.
Referring to each of these 1A, 1B, and 1C collectively, it may be seen that in each embodiment the hand shield 10 is designed to be attached to a sleeve 22. The sleeve 22 may form part of a protective garment 24 as depicted in FIG. 1A. Alternatively, the sleeve and hand shield combination may be used by itself, that is, without requiring its use with a protective garment as depicted in FIGs. 1B and 1C. Irrespective of its use, in many embodiments, the hand shield 10 is connected in proximity to the hand end or distal portion 26 of the sleeve 22 which may include being attached to a sleeve cuff 28 should the sleeve 22 possess a cuff 28. It should be noted that the terms "lower" or "distal" when referring to the sleeve are used to denote features that are closer to the hands of a wearer as differentiated from features that are closer to the shoulder region of the wearer.

The hand shield 10 or at least a portion of the hand shield 10 is designed to detach from the sleeve 22 at a predetermined zone of separation 30. The attachment of the hand shield to the sleeve is configured such that a peripheral opening 32 of the hand shield 10 is aligned with, and shares a border with, a peripheral surface 34 of the distal portion 26 of the sleeve 22. This configuration enables the wearer to extend his hand through the sleeve 22 directly into the hand shield 10. In many embodiments the zone of separation 30 is positioned on the outside or exterior surface of the sleeve so that the distal portion 26 of the sleeve 22 or the sleeve cuff 28 is occluded by the hand shield. Alternatively, the sleeve 22 may form the exterior surface if desired and the hand shield attached to an inner surface of the sleeve.

The zone of separation 30, is that region specifically designed to fail thus enabling the intentional separation of the hand shield 10 from the sleeve 22. The zone of separation 30 is configured so as to minimize the generation of loose particulate. In one embodiment, the hand shield 10 is made to detach from the sleeve 22 by pulling the hand shield with sufficient force resulting in an intentional separation of the hand shield 10 or at least a portion thereof from the sleeve 22 at the zone of separation 30. The force necessary to separate the hand shield from the sleeve is dependent upon a number of controllable design parameters including: the materials selected in the manufacture of the sleeve; the materials used in the manufacture of the hand shield; and the manner and/or form with which the hand shield is attached to the sleeve. In some embodiments, a portion of the hand shield may remain attached to the sleeve or sleeve cuff. In such embodiments safeguards should be incorporated into the design in order to minimize the potential for the remaining portion of the hand shield to otherwise negatively impact the sterility of the subsequently donned gloves. Such methods are discussed below.
It should be appreciated that the type of fabric or material used for the sleeve 22 is in no way a limiting factor of the invention. The sleeve may be made from a multitude of materials, including nonwoven materials suitable for disposable use. For example, if the sleeve 22 of a protective garment 24 were used with or designed to form a part of a surgical gown, the sleeve 22 may be made of a nonwoven material less likely to tear during donning or wearing. One material particularly well suited for use with the present invention is a three-layer nonwoven material known as SMS or Spunbond-Meltblown-Spunbond laminate. See for example U.S. Pat. No. 4,041,203 to Brock et al. One particular advantage is that SMS exhibits enhanced fluid barrier characteristics making it especially desirable for use in a surgical setting. It should be noted, however, that other nonwovens in addition to other materials including wovens, knits, films, foam/film laminates, and combinations thereof may be used in the construction of the present invention.

Looking still to FIGs. 1A-C, as stated above, the sleeve 22 may incorporate a cuff 28 attached to the distal portion 26 of the sleeve 22. The configuration of the cuff 28 and the materials used in its construction may vary widely. For example, cuffs made from a knitted material may be provided. The cuff 28 may be formed with or without ribs. The cuff may be formed of a liquid repellent material or a liquid retentive material. Examples of other cuff materials suitable for use with garments according to the present invention may be nonwovens such as those described in U.S. Pat. Nos. 5,594,955 and 5,680,653, both of which are incorporated herein in their entirety for all purposes.

The hand shield itself may also be manufactured from a number of suitable materials. For example, the sleeve material may be used to manufacture the hand shield. That is, if the sleeve is made of a nonwoven material, then the hand shield may be made of the same material. This capability would serve to minimize the materials necessary in manufacturing the final product. Moreover, it may provide for a simpler construction in that there would be no need to accommodate a method or construct capable of attaching different materials possessing, perhaps, disparate properties.

Other materials are suitable in the construction of the hand shield 10. By way of example and not limitation, two such materials may include polyethylene and vinyl. These materials provide the advantage of being inexpensive and easily adapted for use in the present invention. For example, polyethylene may be formed into a film ply which subsequently could be sealed upon itself or to another ply so as to form the pouch-like compartment.
Sealing methods may include the application of heat, adhesive, or both. In the case of vinyl, a hand shield may be made using dip forming techniques in conjunction with a platisol and appropriate heat treatments, known to those skilled in the art. One such example may be found in U.S. Pat. No. 5,881,386 which is incorporated herein in its entirety for all purposes. Other techniques for affixing one ply to another or for otherwise creating the pouch-like compartment are known and would be understood by those skilled in the art.

As for the manner or form in which the hand shield is attached to the sleeve, a number of possibilities are contemplated. In some embodiments, the hand shield may be affixed to the sleeve simply by use of an appropriately selected bonding agent or combination of agents. One such bonding agent might comprise an adhesive, for example, a hot melt or pressure sensitive adhesive. Alternative bonding agents may be utilized as well. The hand shield also may be affixed to the sleeve by other means, alone or in combination. Such other means include but are not limited to: sewn stitching; fused regions which may be created by the partial melting and resolidification of selected regions of the hand shield and/or a portion of the sleeve or sleeve cuff; contiguous connections such as regions of material separated or otherwise alternated with voids or perforations. Turning now to FIGs. 2-5, a few of these possibilities are illustrated. By way of example and not limitation; these configurations, combinations of the same, and other suitable arrangements are understood to form a part of the present invention. Additional forms of fastening the hand shield to the sleeve to foster the intentional separation of the hand shield from the sleeve without generating loose particulate, including thermal bonding, pressure bonding, chemical bonding, radiation induced degradation of a selected material, etc., would be apparent to those skilled in the art. An aspect that each of these methods of fastening have in common is that the connection between the hand shield and the sleeve is designed to fail or fracture thereby separating the two components from one another in some manner.

Looking first to FIG. 2, the hand shield 10 is shown affixed to the sleeve 22 at the zone of separation 30. As stated earlier, the zone of separation is designed to fail thereby fostering the intentional separation of the hand shield 10 from the sleeve 22. The bonding agent, in this embodiment an adhesive 36, is situated between an inner surface of the hand shield and the outer surface of the sleeve. Of course, as stated earlier, there is no requirement that the bonding agent be an adhesive, however in the FIG. 2 embodiment an adhesive is described for ease and clarity. The adhesive 36 selected should enable the hand shield to
be removed from the sleeve without causing damage to or leaving loose particulate on the sleeve. Whether the adhesive remains behind on the sleeve is not important so long as it is sufficiently adhered so as not to shed or otherwise inadvertently release from the sleeve at an inopportune time. As earlier stated, appropriate adhesives found useful in the present invention may comprise pressure sensitive adhesives, hot melt adhesives, or other adhesives compatible with the materials of the sleeve and hand shield having the properties described above.

In the FIG. 2 embodiment, placement of the adhesive may be accomplished by coating, spraying, printing, slot coating, laminating or other known conventional processes. The adhesive may be applied to one surface of the hand shield 10, the corresponding surface of the sleeve 22, or both. This includes either the inner surface or the outer surface of either the hand shield or sleeve. In sum, the adhesive of FIG. 2 should be disposed between the hand shield and the sleeve. It is to be understood that if the sleeve 22 has a cuff 28, then the adhesive may be applied to the cuff as well. As one example, the adhesive may be applied to an interior surface of the hand shield 10 and a portion of the hand shield may be allowed to occlude a portion of the sleeve. In FIG. 2, the location of the adhesive also forms the zone of separation 30, in that appropriate selection of the adhesive 36 will result in the zone of separation 30 failing when the hand shield is disassociated from the sleeve by pulling on the hand shield. Adhesives are available and may be selected so that the adhesive would adhere more strongly to the hand shield resulting in little to no adhesive remaining on the sleeve. If desired, an appropriate adhesive may be designed that would adhere more strongly to the sleeve if it were so desired.

It should be noted that in many cases, such as that illustrated in FIG. 2, the location of the bonding agent and the zone of separation 30 coincide. In other embodiments, for example, that of FIG. 3, the zone of separation 30 may be separate and distinct from the region where the sleeve and hand shield are attached to one another. Turning to FIG. 3 it can be seen that perforations 40 have been added at or near the bonding agent, i.e., the region where the sleeve and hand shield are attached to one another. These perforations 40 work in a manner identical to those seen in paper products, i.e., they form a focal point for tearing to propagate. As can be seen in this embodiment, the perforations may be used in combination with any bonding agent, including the adhesive 36 similar to that described in FIG. 2.
This manner of attaching the hand shield to the sleeve illustrates one example of an embodiment that permits a partial removal of the hand shield. That is, in the FIG. 3 embodiment, a band of material 42 is caused to remain attached to the sleeve. For example, as depicted in FIG. 3, the hand shield 10 may be situated so that it is attached to an inside surface of the sleeve 22. Pulling the hand shield detaches it from the sleeve at the perforations 40 while leaving behind the band of material 42 which is attached to the sleeve by the adhesive 36. Since the band of material 42 is within the sleeve, it is occluded by the sleeve and is therefore of little threat to the aseptic conditions desired. As can be seen, the zone of separation 30, in this case comprises the perforations 40 and not the region of attachment between the sleeve and hand shield.

Obviously, the FIG. 3 embodiment may be adapted to place the hand shield upon the exterior of the sleeve. In this case, some means to minimize potential impact of the band of material 42 on the sterility of the combination is required. Such means may include: subsequent removal of the band of material 42; sufficiently adhering the band of material 42 to the sleeve so as not to interfere with the procedure intended; and/or manufacturing the combination so that the band of material 42 is ultimately occluded by the sterile glove later donned.

FIG. 4 depicts the use of an embodiment without resort to a bonding agent. One example of this embodiment, the zone of separation 30 is coincident with a groove 44 or other necked region between the hand shield and the sleeve. A number of methods may be employed that create a weakened zone or region between the hand shield and the sleeve. A partial listing of some examples include but are not limited to: perforations; grooving or thinning of the material under a compressive force or thermal source; providing a frangible connection; partially melting and resolidifying selected regions of the garment; radiation induced degradation of selected regions of the garment, including the use of infrared, visible, and ultraviolet light spectra, etc. Such methods for creating a weakened zone or region in a material would be apparent to those skilled in the art. This configuration may be particularly useful if the sleeve and hand shield were manufactured from the same or similar materials, for example, a nonwoven web. As should be evident from this illustration, pulling upon the hand shield causes it to separate from the sleeve between the perforations.

FIG. 5 depicts yet another embodiment. In this embodiment the hand shield is sewn or otherwise stitched to the cuff 28 at the juncture of the cuff 28 and the sleeve 22. Many
protective garments incorporate cuffs upon the gown sleeves. Moreover, it is common practice in the art to sew or stitch the cuff to the sleeve. As such, sewing the hand shield to the sleeve cuff, even at a region coincident with the juncture of the cuff 28 and the sleeve 22 should prove reasonably simple to incorporate into the manufacturing process.

In addition to these enumerated embodiments, numerous other methods for attaching the hand shield to the sleeve are possible. Each embodiment is characterized by possessing a zone of separation designed to fail. It is the failure of this zone of separation that enables the hand shield or at least a portion of the same to be removed from the sleeve. These and numerous other embodiments, as well as combinations of any particular feature in these enumerated embodiments are capable of being combined with any other aspect of one or more of the other embodiments.

This invention makes it easier to don a sterile glove in an unassisted manner. For example, in one donning method, the hand shield is attached to the sleeve so that when a wearer's hand and arm are inserted into the sleeve, the hand fully engages the hand shield. However, the hand shield may be positioned on the sleeve so that the sleeve cuff obstructs a portion of the wearer's hand, that is, it may terminate across the palm of the wearer's hand. Alternatively, it is possible for the sleeve cuff to terminate at the wearer's wrist when the hand shield is donned. In either event, this minimizes the amount of the wearer's hand outside of the sleeve itself and, in both instances, the wearer's hand is still at least partially contained within the hand shield. In each case, the wearer may gain additional dexterity and desirable hand placement, either of which enable easier unassisted donning of sterile gloves.

It should be apparent that this invention is especially well adapted to be used for the unassisted donning of gloves in place of or in simplifying either the open or closed donning techniques. Accordingly, while this invention has been described by reference to certain specific embodiments and examples, it will be understood that this invention is capable of further modifications. This application is, therefore, intended to cover any variations, uses or adaptations of the invention following the general principles thereof, and including such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and fall within the limits of the appended claims.
We claim:

1. A protective garment, comprising:
   a garment body having sleeves, each sleeve terminating in an open end;
   a hand shield attached to at least one of the sleeves, the hand shield comprising a
   pouch-like compartment having a peripheral opening aligned with and
   having a common border with a peripheral surface of the sleeve adapted to
   receive a portion of a wearer's hand therethrough and contain the same
   within the compartment;
   wherein at least a portion of the hand shield is detachable from the sleeve at a
   zone of separation without damaging the sleeve.

2. The garment of claim 1, wherein the garment body is selected from the group
   consisting essentially of medical gowns, clean room garments, and work wear.

3. The garment of claim 1, wherein the hand shield comprises a film formed into a pouch-
   like compartment.

4. The garment of claim 1, wherein the hand shield comprises the same material as the
   sleeve material.

5. The garment of claim 1, wherein the physical configuration of the hand shield is
   selected from the group consisting essentially of a glove, a mitt, and a pouch.

6. The garment of claim 1, comprising a bonding agent for attaching the hand shield to
   the sleeve.

7. The garment of claim 6, wherein the bonding agent comprises an adhesive.

8. The garment of claim 6, wherein the bonding agent is applied to a region coincident
   with the zone of separation.

9. The garment of claim 1, wherein the zone of separation comprises a region capable of
   failure thereby separating the hand shield from the sleeve without generating loose
   particulate.

10. The garment of claim 1, wherein the hand shield is attached to the sleeve by any
    combination of the use of a bonding agent, perforations, thermal bonding, pressure
    bonding, chemical bonding, a frangible connection, and mechanical fasteners.
11. The garment of claim 1, wherein a bonding agent is applied to an inside surface of the hand shield such that a portion of the sleeve is occluded by a portion of the hand shield.

12. A protective garment, comprising:
   a sleeve having an interior region, an opening, and a peripheral surface;
   a hand shield having an interior region and a peripheral opening, the peripheral opening of the hand shield is attached to and shares a common border with the peripheral surface of the sleeve enabling direct access between the interior regions of the sleeve and the hand shield;
   wherein at least a portion of the hand shield is detachable from the sleeve at a zone of separation without damaging the sleeve.

13. The garment of claim 12, wherein the zone of separation comprises the attachment between the hand shield and the sleeve.

14. The garment of claim 12, comprising a bonding agent for attaching the hand shield to the sleeve.

15. The garment of claim 12, wherein the hand shield comprises the same material as the sleeve material.

16. The garment of claim 12, wherein the zone of separation comprises a region capable of failure thereby separating the hand shield from the sleeve without generating loose particulate wherein the hand shield comprises a film formed into a pouch-like compartment.

17. The garment of claim 12, wherein the hand shield is attached to the sleeve by any combination of the use of a bonding agent, perforations, thermal bonding, pressure bonding, chemical bonding, a frangible connection, and mechanical fasteners.

18. The garment of claim 12, wherein a bonding agent is applied to an inside surface of the hand shield such that a portion of the sleeve is occluded by a portion of the hand shield.

19. The garment of claim 14, wherein the bonding agent is applied to a region coincident with the zone of separation.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A41D19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched: (classification system followed by classification symbols)

IPC 7 A41D A61F B25J A62B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
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<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents:
* A* document defining the general state of the art which is not considered to be of particular relevance
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[X] document member of the same patent family

Date of the actual completion of the international search: 12 May 2005

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From: PCT/SA/010 (second sheet) (January 2004)
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