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(54) Title: ABSORBENT DEVICE

(57) Abstract: Shaped polyurethane devices produced by crushing a polyurethane foam at an elevated temperature for a pre-set period of time to set the device in the desired shape.

ABSORBENT DEVICE

The present invention relates to absorbent devices especially absorbent devices for woundcare and feminine hygiene. The present invention also relates to packing devices especially surgical packing devices.

Sponges and other packing materials used for woundcare and feminine hygiene devices require a high degree of absorptivity. Having a device with a high level of absorptivity is particularly important for surgery of the nose, or nasal haemorrhages in general, since there are branches of several arteries located quite close to the surfaces of the nasal septum and other areas of the nasal cavity.

There are a number of materials and devices commonly used for such woundcare, surgery and feminine situations. One commonly used type of material is gauze packs; however, gauze packs have many disadvantages and are known to cause damage to body tissue, for example, nasal lining, during insertion and removal. As the gauze packs absorb blood and other blood fluids, they become progressively less pliable (and stiffer), thus tending to continue the undesirable abrasive effect.

Other packing materials commonly used are hydroxylated polyvinyl acetal foams, also known by the names of PVAc foams, polyvinyl formal foams and PVA foams. An example of such foams is currently sold under the Trade Name EXPANDACELL and available from Smith & Nephew. Another example of such a foam is sold under the Trade Name MEROCEL available from Xomed.

PVAc foams can be crushed to aid insertion through small orifices and are therefore useful in endoscopic procedures. Being a foam they do not shed fibres; however when in the crushed and dehydrated state,

the foam is hard, which may cause tissue abrasion on insertion. There is also a tendency for the foam to absorb at too high a rate causing swelling during insertion and leading to complications. Adhesion to the wound surface has been a problem in the past resulting in pain on removal and further damage to the tissue.

Soft absorbent polyurethane foams are also used for surgery in sensitive areas, for example, in nasal procedures, to reduce the effects of abrasion seen when other materials are used. However these polyurethane foams cannot be preshaped by crushing, like the PVAc foams.

Thus, there exists the need for a wound packing, nasal packing, sinus packing and ear packing, having a soft outer surface for insertion into wound, nasal sinus and ear cavities. There is also another need for an easily removable wound, nasal, sinus and otic packing to eliminate or reduce uncontrolled debridement wound of the nasal, sinus and otic cavity wall surfaces while still allowing removal of exudate from these surfaces.

There is thus a need for an absorbent device that can be preshaped by crushing but will still be soft and pliable.

It is an object of the present invention to address the problems of the prior art. More directly it is an object of the present invention to produce a polyurethane foam that may be substantially preshaped by crushing but when preshaped will still be substantially soft and pliable.

Surprising, the present invention is based on the discovery that by crushing a polyurethane foam to the desired shape and heating the polyurethane foam at an elevated temperature for a relatively short period of time, that on cooling, the polyurethane foam is found to

substantially retain its crushed shape but is still substantially soft and pliable.

According to the present invention there is provided a polyurethane device obtainable by crushing a polyurethane foam to a desired shape and heating the crushed polyurethane foam at an elevated temperature.

According to the present invention there is provided a shaped polyurethane device produced by the method of crushing a polyurethane foam sample to a desired shape and heating the crushed polyurethane foam at an elevated temperature for a pre-set period of time to set the device in the desired shape.

Also according to the present invention there is provided a method of manufacturing a polyurethane device comprising the step of;

crushing a polyurethane foam to a desired shape and heating the crushed polyurethane foam at an elevated temperature.

One embodiment of above include where the polyurethane foam is heated whilst it is being crushed.

Also according to the present invention there is provided a shaped polyurethane device produced by the method of crushing a polyurethane foam sample to a desired shape and heating the crushed polyurethane foam at an elevated temperature for a pre-set period of time for absorption of fluids.

The invention will work for any type of polyurethane foam and this may be linear-chain polyurethane foam. Preferably the foams will be hydrophilic and flexible. The polyurethane foams may be polyester and/or polyether polyurethanes, (inter alia).

The polyurethane foam can be crushed to almost any predetermined shape, or configuration, required, thus having considerable advantage for different dressing types required for easy insertion to wound, nasal, sinus or ear cavities.

The pressure, temperature and time period for the heating process to heat the crushed polyurethane foam whilst it is in its desired shape, is any pressure, temperature, and duration, such that when on cooling the foam, the foam will substantially retain its shape.

Suitable pressures, temperatures and durations for the heating process will depend on the size of the polyurethane samples as larger samples may require more heating. Likewise the pressure, temperature and duration time are related and dependent on each other. When a higher heating temperature is used in the heating process a shorter duration time may be required than when a lower heating temperature is used. Also when a high pressure is used during the heating process, the heating temperature and time period for the heating process may be less than when a low pressure is used during the heating process. Similarly the type of polyurethane foam, the shape of the foam and the means of crushing the foam may all affect the required temperature and duration of the heating process. The physical pressure on the crushed foam may also effect the requirements for the heating process.

Therefore suitable temperature ranges for heating the polyurethane foam may be between 45°C and 200°C, or 45°C and 95°C, or between 45°C and 85°C, or between 50°C and 75°C, or between 60°C and 75°C. Preferably the temperature for the heating of the polyurethane foam will be greater than 50°C and more preferably greater than 55°C. It is envisaged that for many smaller polyurethane

foam samples being heated that a temperature of around 70°C will be a suitable temperature for the heating process.

The heating process may range from a few seconds to several hours. Suitable durations for the heating process may be between 1 second and 7 hours, or between 2 seconds and 4 hours, or between 5 minutes and 120 minutes, but preferable the time period for the heating process will be less than 120 minutes and more preferably less than 60 minutes. Suitable durations for the heating process are between 5 minutes and 50 minutes, or 5 minutes and 40 minutes or 5 minutes and 30 minutes. Suitably the duration of the heating process may be around 10 minutes.

Thus when combined, the heating process, at atmospheric pressure, may have a heating temperature between 50°C and 80°C for around 15 minutes, or between 60°C and 75°C for around 12 minutes, or between 65°C and 75°C for around 10 minutes. Suitably the heating process will have a temperature greater than 30°C and a duration less than 25 minutes. Typically the heating process will have a temperature of around 70°C and a heating duration of around 10 minutes. Aptly the heating process will have a temperature of 100°C and a heating duration of 5 minutes. Other heating processes regarding temperatures, pressure and time, can be readily ascertained by the skilled person without undue experimental burden.

Any means to cut and shape the polyurethane foam before the heating process may be used to shape the foam to the required configuration. Suitably the foam may be pushed or pulled into hollow body of the desired shape. Suitably this container may be a tube. In alternative embodiments of the present invention the polyurethane foam may be crushed and then cut to the desired shape before use.

The cooling mechanism of the heat treated polyurethane foam may be any known cooling mechanism. This may include flash cooling.

In further embodiments of the present invention the polyurethane foam may have one or more film layers attached to one or more of its surfaces. These films may include polyurethane films but any suitable film attached to the polyurethane foam may be used. Suitable films include any flexible polymer including flexible block co-polymers. Preferably the film is elastomeric. The film may also contain perforations to aid fluid absorption. The film may also be non-adhering.

The foam of the present invention may act as a carrier for active agents. By the term active agents it is meant pharmacological active agents and agents including topical anaesthetics such as amethocaine, xylocaine; bacteriostatic agents such as silver nitrate; antibacterial agents of which preferred agents include silver sulphadiazine, chlorohexidine salts, PVP-1, and biguanides antibiotics; topical steroids, enzyme stimulants, coagulants and anticoagulants and antifungal agents.

The invention will now be described by way of example only with reference to the accompanying drawings.

Figure 1 shows a sample of a polyurethane foam before crushing.

Figure 2 shows the foam of Figure 1 partially inserted into a tube.

Figure 3 shows the polyurethane foam of Figure 1 inserted fully into the tube.

Figure 4 shows a polyurethane foam suitably shaped for use as an ear wick.

Figure 5 shows a polyurethane foam suitably shaped for use as a fenestrated ear wick.

Figure 6 shows a polyurethane foam suitably shaped for use as an ear pack.

In Figure 1 there is shown a polyurethane foam (1) with a 1mm diameter hole (2) cut through it in order to enable the polyurethane foam to be pulled through a tube when a surgical suture (3), or the like, is threaded through the hole.

In Figure 2 there is shown the foam (1) partially inserted into a transparent tube (4) as the suture, or thread, is pulled through the tube.

Figure 3 shows the polyurethane foam (1) completely inserted into a transparent tube (4) ready for the heating process.

Example 1

A polyurethane sample measuring approximately 17mm wide and 35mm long was cut from a commercially available (polyurethane) ALLEVYN™ dressing. A 1mm diameter hole was cut into the polyurethane sample and a surgical suture, of approximately 10cm long was threaded through the hole. The polyurethane sample was pulled, with the aid of the surgical suture, into a 1ml syringe. The internal diameter of the syringe is approximately 5mm. The syringe together with the polyurethane sample was then heated in an oven at 70°C for approximately 10 minutes. After heating in the oven the syringe containing the polyurethane sample was removed from the oven and allowed to cool at room temperature. Once cool, the compressed foam

was removed from the tube and it substantially retained its compressed shape.

Example 2

A polyurethane sample shaped as shown in Figure 4, with a length of 11.5mm and a diameter of 7mm was cut from a commercially available (polyurethane) ALLEVYN™ dressing.

The cut sample was placed into a heat shrinkable tubing (initial internal diameter 6mm). The heat shrinkable tubing is generally used in electrical wiring. The heat shrinkable tubing has a theoretical shrink ratio of 3:1 (i.e. should shrink to 2mm ID). Resistance from the foam limited the shrink to 4mm (i.e. ratio of 3:2). The heat shrinkable tubing shrinks evenly in diameter, producing a uniform compression, which produces a well-shaped sample that expands uniformly (i.e. at fairly constant rate at all points of the compressed item) on hydration.

To shrink the sleeve, the sleeve with cut sample was placed in a fan assisted oven at 120°C for 2 minutes, then to 'set' the foam, the sleeve and foam were then transferred to another fan assisted oven, set at 85°C, for a further 10 minutes.

The sleeve containing the polyurethane sample was removed from the oven and allowed to cool at room temperature. Once cool the compressed foam was removed from the sleeve. The compressed foam substantially retained its compressed shaped and was also substantially soft and pliable. Such foams of this shape may suitably be used as Ear Wicks. The final crushed shape was approximately 4mm in diameter and 13mm in length.

Example 3

A polyurethane sample as described in Example 2 was placed into a heat shrinkable tubing (initial internal diameter 6mm). The heat shrinkable tubing had a theoretical shrink ratio of 3:1 (i.e. should shrink to 2mm ID). To shrink the sleeve, the sleeve with cut sample was placed in a fan-assisted oven set at 120°C for 2 minutes. The sleeve containing the cut sample was then placed into another heat shrinkable tubing (initial ID 4.8mm, shrink ratio 2:1). This was then placed in another fan-assisted oven, set at 85°C, for a further 10 minutes.

After the final heating the sleeve containing the polyurethane sample was removed from the oven and allowed to cool at room temperature. Once cool, the compressed foam was removed from the sleeve. The compressed foam substantially retained its compressed shape and was also substantially soft and pliable. The final crushed sample was approximately 3mm in diameter and 13mm in length.

Example 4

A polyurethane sample shaped as shown in Figure 5 was cut from a commercially available (polyurethane) ALLEVYN™ dressing. The precrushed dimensions of the cut polyurethane were 7mm external diameter, 11.5mm in length and the central hole had a diameter of 4.6mm. Foam of this shape once treated may suitably be used as Fenestrated Ear Wicks.

The cut sample was placed into a heat shrinkable tubing (initial internal diameter 6mm). The heat shrinkable tubing is generally used in electrical wiring. The heat shrinkable tubing has a theoretical shrink ratio of 3:1 (i.e. should shrink to 2mm ID). Resistance from the foam limited the shrink to 4mm (i.e. ratio of 3:2). The heat shrinkable tubing

shrinks evenly in diameter, producing a uniform compression, which produces a well-shaped sample that expands uniformly (i.e. at fairly constant rate at all points of the compressed item) on hydration.

To shrink the sleeve, the sleeve with cut sample was placed in a fan assisted oven at 120°C for 2 minutes, then to 'set' the foam, the sleeve and foam were then transferred to another fan assisted oven, set at 85°C, for a further 10 minutes.

The sleeve containing the polyurethane sample was removed from the oven and allowed to cool at room temperature. Once cool the compressed foam was removed from the sleeve. The compressed foam substantially retained its compressed shaped and was also substantially soft and pliable. The final crushed shape was approximately 3.5mm in external diameter, 13mm in length and the internal hole having a diameter of 1mm.

Example 5

A sample similar to that described in Example 4 was used.

The cut sample was placed into a heat shrinkable tubing (initial internal diameter 6mm). The heat shrinkable tubing had a theoretical shrink ratio of 3:1 (i.e. should shrink to 2mm ID). To shrink the sleeve, the sleeve with cut sample was placed in a fan-assisted oven set at 120°C for 2 minutes. The sleeve containing a sample was then placed into another heat shrinkable tubing (initial ID 4.8mm, shrink ratio 2:1). This was then placed in another fan-assisted oven, set at 85°C, for a further 10 minutes. After the final heating the sleeve containing the polyurethane sample was removed from the oven and allowed to cool at room temperature. Once cool, the compressed foam was removed from the sleeve.

Again the compressed sample substantially retained its compressed shape, having approximately an external diameter of 2mm and a length of 13mm. The compressed sample was also substantially soft and pliable.

Example 6

A cylinder of hydrophilic foam (diameter: 15mm; length: 20mm) was tightly wrapped with a length of a perforated polyurethane wound contact layer (wcl). The wrapped foam was placed between two sheets of s siliconised release paper, and passed 'sideway' (longest dimension parallel to the laminating roller axis) through a heated laminating unit (Laminex International Ltd., model DTL A4). The laminator had an operating temperature of 150°C and the wrapped foam was passed through the laminator at a speed of 0.67m/min. Even though the wcl was tightly wrapped around the foam, doe to the compression of the foam, there was always a 'flange' of wcl on the leading and trailing edges. In order to obtain a neat finish and improve lamination, the excess material was trimmed to ~2mm and wrapped around the foam. The foam cylinder was turned through 90 degrees on its long axis and passed through the laminator again.

The sample was placed in the centre of a length of plastic braid material. The nominal diameter of the plastic braid material was 5mm, though it was expanded to around 15mm diameter to envelop the pack. The braid was then pulled into a plastic tube, a pipette body (internal diameter 8mm) to compress the cut sample foam.

The whole assembly was 'cooked' in a fan assisted oven at 85°C for 5 minutes to achieve a temporary 'set'. 10 minutes after removing from the oven the compressed foam was removed from the tube/braid,

and placed into a length of heat shrinkable tubing. To shrink the sleeve, the sleeve with foam pack was placed in a fan-assisted oven set at 120°C for 2 minutes. To 'set' the foam, the sleeve and foam were then transferred to another fan-assisted oven, set at 85°C, for a further 5 minutes.

Once cool, the compressed foam was removed from the sleeve. The foam substantially retained its compressed shape having approximately a length of 23mm and an external diameter of 7.5mm. The compressed foam was also substantially soft and pliable.

CLAIMS

1. A polyurethane device obtainable by crushing a polyurethane foam to a desired shape and heating the crushed polyurethane foam at an elevated temperature

2. A polyurethane device as claimed in claim 1 in which the polyurethane foam is hydrophilic.

3. A polyurethane device as claimed in claim 1 in which the polyurethane foam comprises polyester and/or polyether polyurethanes.

4. A method of manufacturing a polyurethane device comprising the step of;
crushing a polyurethane foam to a desired shape and heating the crushed polyurethane foam at an elevated temperature.

5. A polyurethane device as claimed in claim 1 in which the crushed polyurethane foam is heated to a temperature between 40°C and 95°C.

6. A dressing or packing made from a polyurethane device according to claim 1.

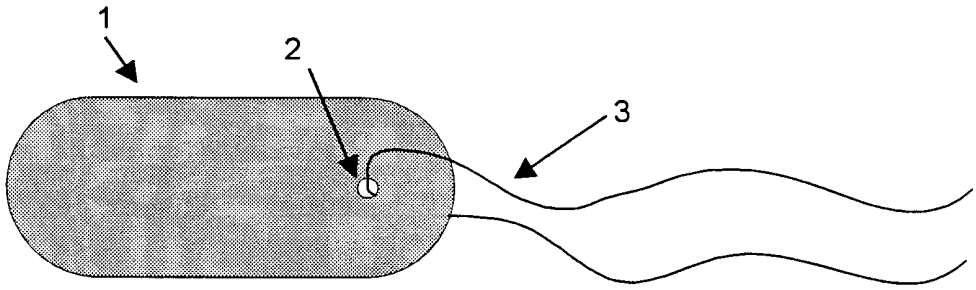


Figure 1

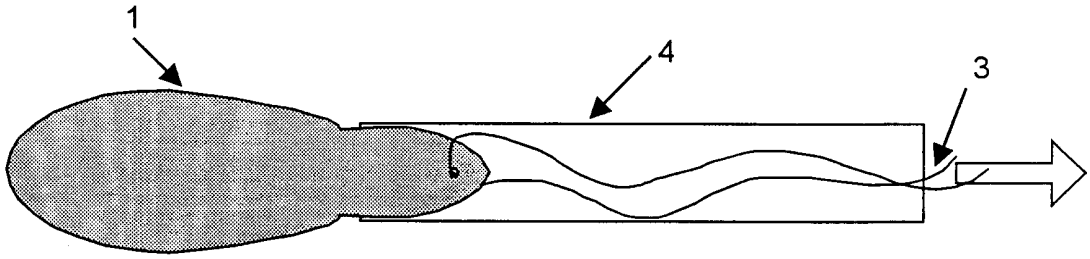


Figure 2

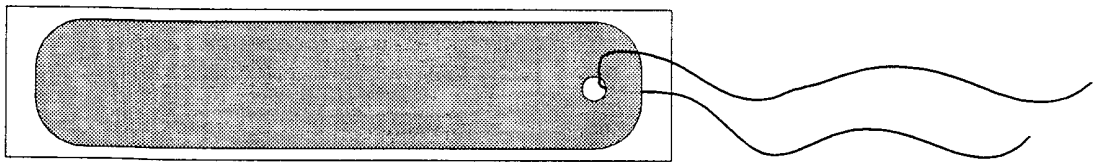


Figure 3

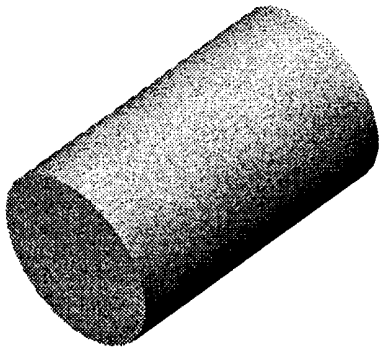


Figure 4

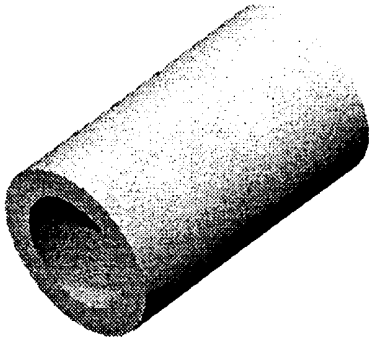


Figure 5

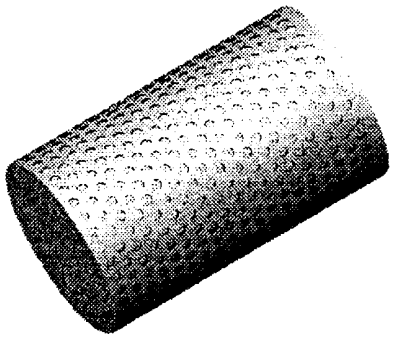


Figure 6