

DEVICE DESCRIPTION

1. Device Description & Features

Ultrasound Transmission Gel is a type of conductive medium that is used in ultrasound diagnostic techniques and therapy treatments. It is placed on the patient's skin at the beginning of the ultrasound examination or therapy. The ultrasound probe, which is the device used to send and receive sound waves, is then placed on top of it. Ultrasound gel is also used with a fetal Doppler, which can be employed to allow parents and doctors to listen to the heart beat of an unborn child. Ultrasound gel is a clear goo, looks like hair gel or aloe vera, and is made from various combinations of propylene glycol, glycerine, carbomer and TEA along with lots of water (L).

2. Intended Use

Ultrasound requires many types of movement by the sonographer. Many of these are subtle and require a frictionless surface to allow the sonographer to obtain the perfect image. Ultrasound gel acts as a lubricant that allows for easy movement of the transducer/ultrasound probe (camera) across the skin.

When air is present, a signal is not returned to the ultrasound machine to create an image. Ultrasound gel removes the air between the skin and the transducer/ultrasound probe so ultrasound waves can move freely between the body and the transducer.

Most ultrasound cameras cannot focus on structures that are too close to the surface of the skin. A thick layer of ultrasound gel can be applied to the skin to distance the camera from the structure for better focus.

3. Indications

N/A

4. Instructions for use

- i) Apply a sufficient amount of gel on the area of interest to keep optimal lubrication.
- ii) Can be directly applied to the probe or transducer.
- iii) Once the scanning procedure is done, wipe off the remaining with a towel.
- iv) The gel is to be kept from direct sunlight and seal properly after use to maintain the hygienic and durability.

5. Storage condition

Store at 10°C-40°C (do not expose to hot sun)

6. Shelf life

3 Years (36 months from date of manufacturing)

7. Contraindications

N/A

8. Warnings

Do not use with defibrillator

9. Precautions

There are no any significant potential undesirable and serious outcomes (death, injury or serious adverse events) to the patient/user, or side effects from the use of this product ultrasound gel, under normal conditions, no any precautions is needed.

10. Potential adverse effects

These are no any significant potential undesirable and serious outcomes (death, injury or serious adverse events) to the patient/user, or side effects from the use of this product ultrasound gel, under normal conditions.

11. Alternative therapy

For skin cosmetic use.

12. Materials

No.	Chemical	Concentration (%)
1	Carbomer	1%
2	TEA	1%
3	Glycerine	1%
4	PEG 400	3%
5	DMDM Hydantoin	1%
6	FD&C Blue	0.0002%
7	DI Water	94%

13. Product specifications

Product Code	Packing Method	Viscosity
SKYLERGEL260B	260g \pm 10g	90-130KcP
SKYLERGEL5000B	260g \pm 10g	90-130KcP
SKYLERGEL260C	5.00 Kg \pm 0.05Kg	90-130KcP
SKYLERGEL5000C	5.00 Kg \pm 0.05Kg	90-130KcP

14. Other Descriptive Information

Refer to SB-TF-01 Skyler Tech File for more details