



OCON

THE NEXT GENERATION IUD: INTRA UTERINE BALL

HIGH-TECH CONTRACEPTION WITH SHAPE MEMORY - FOR UP TO 5 YEARS

Previous intrauterine devices are based on the t-shape, a 40 year old technology.

The IUB™ is a newly developed copper intrauterine device (IUD) with a whole new high-tech design.



The support material for the copper is **Nitinol**, a **memory shape alloy**, that „remembers“ its original shape and when deformed returns to its pre-deformed shape. This special virtue has been successfully used in medicine for a long time, e.g. in implants and stents. **Several copper beads**, with a total exposed copper surface area of **300 mm²**, are strung on a monofilament polymer thread.

The IUB™ is **sphere-shaped** and is available in **3 different sizes** ranging from **12 mm to 18 mm** in diameter. The thread is tied through the tip, resulting in two threads, each at least 10.5 cm in length, to aid in detection and removal of the device.

Before insertion the IUB™ is located in a 3.2 mm (in diameter) insertion tube, that can be inserted almost painlessly without local anesthesia in the cervical canal - even with nulliparous patients.

As soon as the tube is placed correctly and the IUB™ is released, the frame **curls 180 degrees** away from the fundus. **Since the IUB™ frame curls backwards it should be released close to the fundus to avoid expulsion.** Once the IUB™ is placed in the uterus it **forms a 3-dimensional spherical shape**, as shown in the picture on the right. The IUB™ is between one third to a half of the size of traditional intrauterine devices.



THE ADVANTAGES OVER OTHER SYSTEMS ARE:

- easy insertion
- almost no risk of perforation
- less irritation of the endometrium due to the small size, flexibility and the lack of sharp edges

The IUB™ is not approved for sale in the US.



THE INSERTION VIDEO
CAN BE VIEWED AT
www.oconmed.com

INSERTION OF THE INTRA UTERINE BALL

For detailed information please refer to the IFU.

STEP 1

Open the package; Use the gauge to mark on the insertion tube the uterine depth that you measured with the sound. Pass the pre-loaded insertion tube through the cervical canal until the gauge is in touch with the cervical external os.

STEP 2

To release the IUB™ push the rod forwards but avoid pulling the tube back. This releases the IUB™ into the uterine cavity. Since the IUB™ frame curls backwards it should be released close to the fundus to avoid expulsion.

STEP 3

Pull out the rod and then pull out the insertion tube.

STEP 4

Cut the threads about 2 cm out of the cervix.

STEP 5

Perform an ultra-sound examination to make sure the IUB™ is in the center of uterine cavity. If the IUB™ is not positioned completely within the uterus, remove it and replace it with a new IUB™. Do not reinsert an expelled or partially expelled IUB™. Invite the patient for a follow up visit after 2 months. The removal procedure is identical to the removal technique of standard IUDs.

CAUTION

Instrumentation of the cervical os may result in vasovagal reactions, including fainting. Have the patient remain supine until she feels well, and have her get up with caution.

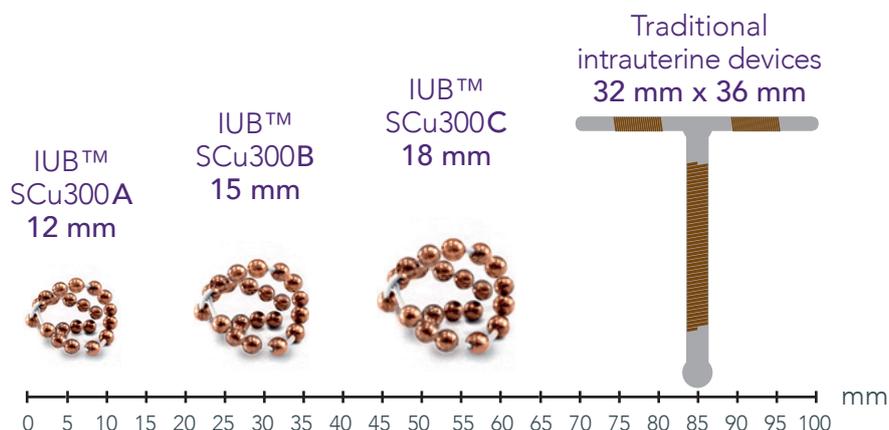


illustration in actual size