

<b>PRODUCT SPECIFICATION:</b> <b>Efemia Bladder Support/ Kontinensstöd/Kontinensstøtte</b>	
Approved by Ulrika Andersson, CCO Arcamea. Sign: 	Valid from: <b>2019-01-01</b>

## 1. PRODUCT DESCRIPTION

Efemia Bladder Support is intended to temporarily relieve stress induced urine leakage in women by supporting the mid urethra through the vaginal wall.

## 2. VERSIONS OF PRODUCT

Efemia Bladder Support, Start-set 30mm, 35mm, 40mm  
 Efemia Bladder Support, 30mm  
 Efemia Bladder Support, 35mm  
 Efemia Bladder Support, 40mm

## 3. LOT NUMBER AND EXPIRY DATE

Lot number: Printed on the bottom of product box sleeve  
 Expiry date: Printed on the bottom of product box sleeve

## 4. SHELF LIFE AND STORAGE CONDITIONS

Temperature(T).	Humidity(RH)	Shelf Life
4°C - room temperature.	No special requirements	≥ 24 months

## 5. PRODUCT MATERIAL

Efemia Bladder Support is made of an injection-molded medical grade two component silicone elastomer, SILPURAN®. In the production of silicones, especially SILPURAN® no phthalates, other organic plasticizers, nitrosamines, latex, plant proteins, organic stabilizers or animal-based materials are added.

SILPURAN® is tested for biocompatibility and complies with current standards for modern medical technology, ISO 10993 and USP Class VI.

Furthermore, the injection molding of Efemia is done without any processing chemicals or additives.

The material is soft and flexible, yet at the same time resilient enough to support the urethra when abdominal pressure rises. The characteristics of the silicone also makes the device robust enough to withstand the vaginal environment, cleaning and reuse.