

Risk of Breast Augmentation

Breast augmentation is a procedure to increase breast size for cosmetic reasons. The current practice is to use breast implants with shell but cases using direct injection with material like PAAG and silicone gel had been reported in Hong Kong and other countries.

Saline implants and silicone gel-filled implants are commonly used breast implant while materials like PAAG and silicone gel have also been reported to be used for direct injection for breast augmentation. There are risks for breast augmentation either with breast implants or by direct injection with materials.

Risks associated with breast implants include hardening of the area around the implant, breast pain, changes in breast and nipple sensation, rupture with deflation of saline implants, rupture with or without symptoms for silicone gel-filled implants, migration of silicone gel from silicone gel-filled implants and additional surgeries required for removal of the device. In some cases, the material cannot be completely removed from the breast.

Risks associated with direct injection include breast lumps, infection, inflammation, bleeding, abscess, pain, change in skin sensation and contour, migration of gel etc. In some cases, the conditions need treatment including complete removal of breasts. Moreover, serious life-threatening conditions such as pulmonary embolism and acute respiratory distress after breast augmentation with silicone injection had been reported.

Implants are classified as medical device (MD) internationally. Specifically, breast implant is classified as Class IV (high risk) MD. At presents, the U.S. Food and Drug Administration has approved only two types of breast implants for marketing in USA namely saline-filled and silicone gel-filled breast implants with the filling material contained in a shell. No injection material has been approved by FDA for breast augmentation.

There is no statutory regulation on breast implants in Hong Kong. However, manufacturers of medical devices including breast implants can apply for voluntary listing under the Medical Device Administrative Control System (MDACS). To date,

several breast augmentation devices are listed under the MDACS of Department of Health (DH).

Local plastic surgeons consider that breast augmentation by direct injection is an obsolete practice and the current practice is to use breast implants with shells. Since the safety of breast augmentation by direct injection is doubtful and serious complications have been reported, DH does not recommend using this method for breast augmentation.

In Hong Kong, all medical treatments and procedures should be performed by registered medical practitioners. Illegal practice of western medicine is an offence that can be sentenced to imprisonment under the Laws of Hong Kong.

Anyone who plans to have breast augmentation should seek advice from medical professionals and the procedure should only be performed by a registered medical practitioner. Anyone who has health problem after breast augmentation is advised to seek medical advice immediately.

Medical Device Division

Department of Health

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Breast Augmentation

Questions & Answers

1. What is breast augmentation?

Breast augmentation is a procedure to increase breast size for cosmetic reasons.

2. Breast Implants vs Injection with materials

According to local plastic surgery specialists, breast augmentation by direct injection with material is an obsolete practice and the current practice is to use breast implants with shells.

3. What are the risks of breast implants?

Some of the risks of breast implants include hardening of the area around the implant, breast pain, changes in breast and nipple sensation, rupture with deflation of saline implants, rupture with or without symptoms for silicone gel-filled implants, migration of silicone gel for silicone gel-filled implant and additional surgeries required for removal of the device. In some cases, the material cannot be completely removed from the breast.

4. What are the risks of breast augmentation by injection with materials?

Risks of breast augmentation by injection with materials include breast lumps, infection, inflammation, bleeding, abscess, pain, change in skin sensation and contour, migration of gel etc. In some cases, the conditions need treatment including complete removal of breasts. Moreover, serious life-threatening conditions such as pulmonary embolism and acute respiratory distress after breast augmentation with silicone injection had been reported.

5. Is there any regulation on material used for breast augmentation?

Implants are classified as medical device (MD) internationally. Specifically, breast implant is classified as Class IV (high risk) MD. At present, the U.S.

Food and Drug Administration has approved only two types of breast implants for marketing in USA namely saline-filled and silicone gel-filled breast implants with the filling material contained in a shell. No injection material has been approved by the FDA for breast augmentation.

There is no statutory regulation on breast implants. However, manufacturers of medical devices including breast implants can apply for voluntary listing under the Medical Device Administrative Control System (MDACS). To date, several breast augmentation devices are listed under the MDACS of Department of Health (DH). Since the safety of breast augmentation by injection with material is doubtful and serious complications have been reported, DH has reservation about this method and does not recommend the public to use this method for breast augmentation.

6. What should I do before deciding to have breast augmentation?

Members of the public should seek advices from registered medical professionals before contemplating breast augmentation. In Hong Kong, all medical treatments and procedures should be performed by registered medical practitioners. Illegal practice of western medicine is an offence that can be punished with imprisonment under the Laws of Hong Kong.

7. How can I know more?

You may visit the website of Medical Device Division of DH at <https://www.mdd.gov.hk> ; or the U.S. Food and Drug Administration at <https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants> for more information. If you have any queries, please consult your family physician for medical advices.