

Collagenase

WHAT IS COLLAGENASE?

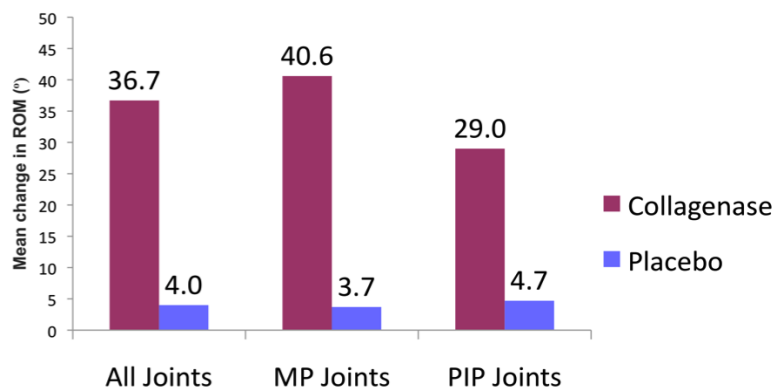
Xiapex ® is the trade name of collagenase clostridium histolyticum which is produced naturally from a bacterium called clostridium histolyticum. Over many years the concept was developed to establish the viability of this alternative technique, then dose ranging studies and then a clinical trial programme to prove its effectiveness.

The drug specifically dissolves the collagen contained within a cord of Dupuytren's Disease. This removes a segment of the cord. Once a segment is removed, the cord no longer tethers down the finger and so the finger can straighten. It is particularly effective for discrete cords across the front of the MP joint (ie the knuckle).



In 2010 it was given approval by the FDA (Federal Drugs Administration) in the USA; in 2011 it was given approval by the European Medicines Agency and then by the UK.

The evidence which led to the approval by the FDA and European Medicines Agency can be seen below



www.ncbi.nlm.nih.gov/pubmed/19726771

<http://www.ncbi.nlm.nih.gov/pubmed/21134613>

<http://www.ncbi.nlm.nih.gov/pubmed/17606053>

www.ncbi.nlm.nih.gov/pubmed/10913202

WHAT HAPPENS WHEN I HAVE XIAPEX® ?

You are assessed in the clinic by Mr Warwick to ensure you are suitable. The deformity of your fingers is measured and you are asked to fill out 2 brief questionnaires to assess your function.

On the day of injection, you are asked to sign a consent form (downloadable in advance). The Xiapex is removed from the Pharmacy fridge an hour before the injection and warms up to room temperature. The two vials (fluid and powder) are then gently mixed. Your hand is sterilized with alcohol and the Xiapex is injected into the cord with a very fine needle. A cold spray is used to minimize the discomfort. A dressing is applied.

Overnight your hand may get quite bruised and swollen- that is normal. The next day you come back to the clinic. Your hand is sterilized again with alcohol. Local anaesthetic is injected around the cord and then the cord is gently manipulated into extension until it snaps.

If the cord does not give way after 3 attempts then you can be scheduled in for a further injection 30 days later, or conventional surgery if you prefer.



CAN I DRIVE OR WORK AFTER THE INJECTION?

You should not drive after the injection of manipulation until you feel safe to control the car in all eventualities. Choosing to drive is your own responsibility and not the Doctor's. However, most people can drive within a few days. The same applies for desk top and light manual work. Heavier work may require up to 2 weeks.

WHAT ARE THE COSTS?

Insured Patients: The insurance companies have applied a code to Xiapex injection: *T 7440: Injection into cord for Dupuytren's Contracture (including post- injection finger extension).*

Self Funding Patients: at The Wessex Nuffield Hospital, there is a fixed price option to cover the cost of a Xiapex injection, including the drug, hospital tariff, surgeon's fee and splint. (see downloadable leaflet). If the injection does not work first time then you would need to pay for the second at a similar rate. An initial consultation with Mr Warwick to see whether you are suitable is £150.

WHAT ARE THE CHANCES OF IT WORKING?

Xiapex is only suitable for certain patients. If you have a discrete cord that is judged amenable to Xiapex, then about 75% chance of a significant improvement with one injection. Some people may need a second injection.

Cords across the MP joint (ie the joint between the palm and the finger) tend to improve better than cords across the PIP joint (ie the finger joints).

Only one finger can be corrected at a time- if you have two involved fingers then they will need an injection on separate occasions.

The recurrence rate is not fully known but is thought to be around 20% at 2 years.

ARE THERE RISKS?

- **Allergic reaction:** about 17% of people may have a mild allergic reaction- - itching or a rash. The armpit nodes may become sore and swollen. There is a theoretical risk of anaphylactic shock (ie sudden collapse with airway obstruction and circulatory collapse). This is exceedingly unlikely and has never been reported with the drug. Nevertheless, adrenaline (the antidote to this) is kept immediately available when the drug is given.
- **Tendon rupture:** *Collagenase will damage tendons if inadvertently injected too deeply. For this reason it is only administered by trained hand surgeons. In the extremely unlikely event that you find that you cannot bend the finger after the injection, let Mr Warwick know.*

According to the data sheet, the following are risks:

Very common side effects: affects more than 1 user in 10:

- reactions at the injection site like bleeding, pain, swelling, tenderness and bruising
- itching in the hand
- feeling of pain in the hand, wrist or arm
- swollen or enlarged glands near the elbow or under the arm
- swelling in the hand or arm

Common side effects: affects 1 to 10 users in 100:

- reactions at the injection site like pain, warmth, swelling, presence of a blister, redness of skin and/or skin rash
- skin wound at the site of injection
- painful glands near the elbows or under the arm
- joint swelling and pain
- burning sensation, partial loss of sensitivity, feeling of "pins and needles" or numbness
- dizziness, headache, nausea
- increased perspiration